Traditional 510(k) SUMMARY K112393
[As required by 21 CFR 807.92(c)]

Date Prepared	16th Aug, 2011
Submitter Name	Mr. Kim Kuan Lee
Official Contact	Mr. David D'Cruz V.P., Medical & Regulatory Affairs 9001 Spectrum Center Blvd San Diego CA 92123 USA Tel: (858) 836-5984
Device Trade Name	Tasman
Device Common Name	Non continuous Ventilator (IPPB)
Classification	21 CFR 868.5905 (Class II)
Product Code	73 BZD
Predicate Device	S8 Prime (K033841) Ultra Mirage II Nasal Mask (K050359)
Reason for submission	New Device
Intended Use	The Tasman is indicated for the treatment of obstructive sleep apnea (OSA) in adult patients weighing more than 66 lb (>30 Kg). The Tasman mask system delivers airflow noninvasively to a user from the integrated Continuous Positive Airway (CPAP) device. The Tasman is intended for single-patient re-use in the home environment and while travelling.
Substantial Equivalence	The new device has the following similarities to the previously cleared predicate devices. • Same intended use • Similar operating principle • Similar technologies • Similar manufacturing process Design and Verification activities were performed on the Tasman System as a result of the risk analysis and design requirements. All tests confirmed the product met

	the predetermined acceptance criteria. This included pressure stability, jitter, swings, ISO 17510-1 pressure performance and functional dead space tests against the predicate devices using common protocols for both devices. ResMed has determined that the new device has not altered the safety and effectiveness of CPAP treatment for adult patients with Obstructive Sleep Apnoea (OSA) who weigh more than 66 lb (>30 kg). The new device complies with the applicable requirements referenced in the FDA guidance documents: • FDA Draft Reviewer Guidance for Ventilators (July 1995)
Device Description	The Tasman is a portable CPAP device where the blower, mask and tubing are integrated and mounted to the headgear. The blower generates the required CPAP pressure to maintain an "air splint" for effective treatment of OSA.
Conclusion	The Tasman is substantially equivalent to the Predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Resmed Corporation
9001 Spectrum Center Boulevard
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Re: K112393
Trade/Device Name: Tasman
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: August 16, 2011
Received: August 19, 2011

Dear Mr. D'Cruz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K112393

Device Name: **Tasman**

Indication for Use

The Tasman is indicated for the treatment of obstructive sleep apnea (OSA) in adult patients weighing more than 66 lb (>30 Kg). The Tasman mask system delivers airflow noninvasively to a user from the integrated Continuous Positive Airway (CPAP) device. The Tasman is intended for single-patient re-use in the home environment and while travelling.

Prescription Use ___X___ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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